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AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION, AND RELATED
AGENCIES APPROPRIATIONS FOR 2001

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG
ADMINISTRATION, AND RELATED AGENCIES

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND
RELATED AGENCIES APPROPRIATIONS FOR 2001

Tuesday, February 29, 2000.

FOOD AND DRUG ADMINISTRATION

WITNESSES

DR. JANE HENNEY, COMMISSIONER

DR. BERNARD SCHWETZ, ACTING DEPUTY COMMISSIONER

ROBERT J. BYRD, DEPUTY COMMISSIONER FOR MANAGEMENT AND SYSTEMS, CHIEF
FINANCIAL OFFICER, FOOD AND DRUG ADMINISTRATION

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF
HEALTH AND HUMAN SERVICES

DR. JANET WOODCOCK, DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH

JOSEPH A. LEVITT, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED
NUTRITION

DAVID FEIGAL, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Mr. Skeen. The committee will come to order. We have before us today the Food and Drug Administration very ably represented by Commissioner Jane Henney and her associates, and I am sure that they are well prepared to respond to our questions about FDA's operations and activities. Before we recognize Dr. Henney for her remarks I would like to welcome Ms. Kaptur.

Ms. Kaptur. Thank you, Mr. Chairman, and we are so pleased to have the Commissioner and her able staff here this morning. I just want to say to the chairman I am so impressed with this Commissioner and her quick response and her staff's quick response whenever we have attempted to obtain information about FDA. We thank her for that, for her professional service to the people of this country, and we look forward to her testimony. On behalf of all the members on this side of the aisle, Commissioner Henney, thank you very much for being here this morning.

Mr. Skeen. Commissioner, we have received your prepared remarks and they are excellent and thorough as always, and they will appear in full in the record of this hearing. We would ask for you to summarize the highlights.

Opening Statement

Dr. Henney. Mr. Chairman and members of the committee, it is my privilege today as Commissioner of Food and Drug to present FDA's plans and expectations as reflected in the administration's proposed budget for fiscal year 2001. One year ago I told you that I was lured from the enchantments of New Mexico to renewed public service by the dedication, energy and commitment of the talented people in FDA. I was equally attracted by the enormity of the changing demands upon the agency and the differences this agency can make in improving the public health.

Patients, researchers, health professionals, manufacturers,

educators, grocers, public sector administrators or just ordinary citizens want a public health regulatory agency such as the FDA to be fair, competent, and above all credible. I have heard this message in different words on many occasions in many settings this year. I believe the accomplishments of this past year will demonstrate that FDA has done a remarkable job in maintaining the public's confidence and credibility even though we face numerous unpredictable issues on a day-to-day basis.

It may be far too easy for Americans to assume FDA's competence and credibility because we have long enjoyed public confidence in the past. However, from listening to my European counterparts, public confidence once lost is not easily or quickly restored.

A series of highly publicized crises in Europe over the past several years have caused my counterparts to ask what is FDA's secret and how does FDA utilize science and build consensus answers to so many inherently contentious issues?

The answers are not found in FDA's organizational diagrams or job titles. We find ourselves explaining modern day versions of two very old history lessons: What Alexis de Tocqueville reported long ago in Europe about the uniquely open processions for American lawmaking and its modern derivative rulemaking and Dr. Harvey Wiley's discussion with President Theodore Roosevelt at the beginning of the last century about the importance of science based regulatory decisions.

From a world perspective, FDA's utilization of public issue meetings, access to agency information, voting advisory committees, requirements for scientific evidence and reliance on scientific facts in its decision-making process are more uniquely American than we may realize.

The interplay of these features into an independent regulatory function that coexists with prescribed congressional and judicial roles constitutes the most envied regulatory model in the world.

Today I share with you my priorities for preserving this capability and for preserving the agency's commitment to and credibility with the American public. As we begin the 21st century, fiscal year 2001 will be critically important for FDA because so much of our environment is changing rapidly and our capability to understand, adapt and respond will be stretched to new limits. To maintain our strength we must strengthen our science. We must address the highest priority risk. We must engage in effective collaborative and leveraged activities and we must design ever more predictable, timely and transparent regulatory processes.

Stronger science. FDA's commitment to assuring safe products rests squarely on our ability to keep pace with the explosion in scientific advances and then to use our knowledge to assure safe products. We must apply our intellectual capital at every point in the life cycle of the product.

Timing is everything. Wayne Gretzky of ice hockey fame was asked to tell what made him a successful player. He said, I skate to where the puck will be. FDA is in a similar position. We must be able to anticipate and access the cutting edge science that will be needed to regulate the products of future technology. When this is possible, we can apply this science at

the point when the new technology arrives and when it is absolutely essential to steward these products, many of them life saving, to the market.

FDA is the regulatory gateway through which an estimated \$50 billion in annual biomedical research and development investment must pass and be judged. During the President's State of the Union address last month, he noted that innovations in science and technology will be the key to miraculous improvements in the quality of our lives and advances in the economy as we enter the 21st century. He discussed the remarkable fruits of research, much of it taxpayer funded, that promise to improve both our health and the way health care is delivered. You and your colleagues in the Congress have overseen a major expansion of Federal research in recent years and these investments will no doubt pay dividends many times over for all of us.

FDA can deliver when properly resourced. Congress' authorization and support of the Prescription Drug User Fee Act and its reauthorization in the FDA's Modernization Act is a prime example. Review of drugs and biologics in the U.S. is now as fast or faster than anywhere in the world, and this has been accomplished without lowering our very strict and high standard for safety and effectiveness. We want to be able to perform this well in all of our products that require premarket evaluation.

Assuring safety by managing risk. A strong FDA science capability is equally critical in understanding and managing risk associated with products that are already in the marketplace. Each year hundreds of thousands of adverse experiences are reported in association with foods, drugs, and medical devices. When we can apply cutting-edge science to these problems, particularly in cooperation with our health and regulatory partners, as well as those in the regulated industry, we can quickly identify significant risks and minimize them.

In managing risk, FDA has always adhered to the principle that the most serious risks should be addressed first. The idea takes on added meaning given the complexities of our 21st century environment. You will see evidence throughout our budget that the most serious problems are on the top of the list. To illustrate, the medical errors initiative in the budget emphasizes FDA's working with other agencies in the Department of Health and Human Services and with other departments across government as a part of the President's new comprehensive plan to improve health care through the prevention of medical errors and the enhancement of patient safety.

Secondly, drugs marketed and sold from rogue Internet pharmacy sites present real risk for the American consumers. These have been made a priority for FY 2001. Again, we have addressed the most serious risks first as a part of the food safety initiative, provided funding, we will be able to inspect high risk food firms at least once a year. We would continue to do the work supported by Congress in the past which focuses our efforts in the important arena by targeting imported produce that contain microbiological pathogens.

Collaboration and leveraging opportunities. Working with FDA's assets alone is not sufficient to address the complex

risk management challenges that we face. Many of our initiatives in this budget require our agency to work in concert with a broad spectrum of stakeholders to rein in the safety net for the U.S. consumer. A prime illustration of this approach is in food safety.

Because we regulate in a global marketplace, our collaborative efforts must extend beyond our domestic borders. In this regard we collaborate with our foreign regulatory counterparts in joint efforts that include setting standards to reduce the risk of products to the consumer. Whether it is within our domestic borders or beyond, FDA undertakes collaborative initiatives because all parties can unify behind goals that are in the best interest of public health and safety. With such collective efforts we will be able to move our world to better health outcomes.

Open, transparent, predictable regulatory processes. Another key provision of the FDA Modernization Act of 1997 directed our agency to consult with our many stakeholders on an ongoing basis to keep them apprised of our strategies and new product decisions and to generally make them an informed participant in the regulatory process. The relevant principle here is that a confident and well-informed individual or industry also becomes a partner in shouldering the management of risk. We intend to keep these communication channels alive and humming. And in addition to our ongoing dialog with industry and consumers that take place in a variety of settings, this spring we will listen at two formal additional stakeholder forums, the first at Stanford University in March and the second at Duke University in April. At both of these sessions we will no doubt receive suggestions on how to improve our programs by leveraging our resources and further strengthening our working relationships with our constituents.

These 21st century ways of doing business, strengthening science, addressing high risk priorities, collaborating effectively with our partners and leveraging our resources and using open, transparent regulatory processes must be applied across the entire spectrum of product development review and post-market monitoring. When we are able to do this, bolstered by science and augmented by partners who share our goals, American citizens can be confident an effective safety assurance system is in place. FDA's budget proposal for FY 2001 moves us toward that desirable state of affairs.

Before I close my remarks, I would like to briefly highlight for you the key elements of our budget request. This proposal will enable FDA to implement the priorities I have outlined for you today. The request is for \$1,390,831,000 which is \$176 million increase over the FY 2000 enacted level. The request includes \$42 million to enhance the science based review of new health giving products so they can more rapidly enter the marketplace.

\$30 million to enhance the safety of the food supply through strengthening key elements of the President's food safety initiatives. These elements include increasing inspection frequency for high risk food firms, implementation of an egg safety action plan, developing nationwide standards for food safety, and expanding the research activities necessary to support the entire initiative.

\$20 million to replace FDA's obsolete Los Angeles laboratory facility. I would contrast the picture before you that is down here, our L.A. lab, with a new modern facility of Cincinnati that you provided the funding for us for a few years ago. We need this kind of facility in Los Angeles because it is a critical linchpin in assuring the safety of a major portion of U.S. imports, particularly food, to this country.

[Additional information follows:]

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Dr. Henney. \$15.9 million to strengthen our systems which report on and correct medical errors and adverse event reporting. This is the interagency cooperative effort designed to reduce the estimated 100,000 annual deaths that occur because of medical misadventures or mistakes.

\$13.5 million to focus on domestic inspections of our firms in order to target high risk violators and to come closer to meeting the agency's statutory inspection requirements.

\$10 million to help stop the illegal sale of drugs over the Internet. And finally \$11.5 million as part of the President's comprehensive response to possible bioterrorist attacks. And \$5 million to further the administration's effort to reduce smoking by the youth of our nation.

In summary, Mr. Chairman, fiscal year 2001 is the year in which FDA must cope with the maturation of two of the most massive and significant forces the agency has ever faced. In 2001 the increasing impact of molecular science, genomics in particular, and the information revolution, especially the Internet, and its linkage to an array of real time data and as a new vehicle for commerce that was unimaginable only a few years ago will combine their forces to change how FDA regulated products are discovered, researched, manufactured, distributed, marketed and advertised. When the world around us changes this much, we must be prepared to respond in order to assure that products are still safe for American consumers. Our credibility to provide valid assurance is a risk without strong science, effective collaborations and consultation and even greater openness and transparency in our processes.

I wish to thank the members of this committee, its staff and the staff of the individual subcommittee members for your support this past year. This subcommittee has many legacies from improved agriculture production to safer consumer products to protection of the American farmer. I ask that you add another critically important one to the list, bringing forth the technological promise of the 21st century. If you will provide FDA the resources to do the job, I will commit to you that those funds will be used wisely.

I look forward to the discussions, our discussing this committee to ensure that we are able to fulfill our mission in this challenging environment. Thank you very much.

[The prepared statement of Jane E. Henney, MD, and biographies follow:]

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

medical errors

Mr. Skeen. Thank you, Dr. Henney. We want to welcome you back to the committee. We would like to congratulate you on the completion of your first year as Commissioner of the Food and Drug Administration. I can see from the information that you submitted that you are already developing the building blocks for real improvement at the agency and that management issues are as important to you as they are to the members of this committee.

Let me ask a couple of questions about challenges that you face every day. Starting with medical errors, the Institute of Medicine issued a study on medical errors stating up to 100,000 people per year died due to preventable medical mistakes. What types medical errors could FDA help prevent? What will be FDA's role in this national effort? I think it has been the spear point that we are dealing with today. Go ahead.

Dr. Henney. Thank you, Mr. Chairman. The medical errors and the medical risks that are inherent in them were highlighted in a task force report that the agency issued last May. They were again highlighted, as you have noted, in the Institute of Medicine study, where it is estimated that up to 100,000 people are affected in very serious ways as a result of mistakes or misadventures that happen within the context of our health care delivery system. As those mistakes might be related to products that we regulate in the device, drug, blood or vaccine area, we know that our role is really with respect to having the proper kind of information systems in place. This is necessary so that as things happen in the post market arena that have to do with adverse events, we have the capability not only to receive through appropriate technology those reports, but the capability of analyzing their meaning. If we need to notify the greater health care community about risks to be avoided or even up to and through removing products from the marketplace, we do that from a basis of strong knowledge.

We also will be cooperating in this effort to see that the kind of information that we provide to health providers is as accurate and clear as it can be. One example that has been pointed out on many occasions is issues that may be related to labeling and so-called sound alike drugs. We need to be prepared as drugs move on to the marketplace that we have the means to put these names through the scrutiny of both how they sound, how they look when they are written so that preventive steps can be put in place to avoid mistakes that might occur.

leveraging

Mr. Skeen. Before I ask this next question I want to remind everybody that we are going to hold this to 5 minutes starting with me. You have been working with partners in the state and academia and industry. And this has been stretching the FDA's resources through this leveraging. Can you explain a little bit more about the leveraging concept and to what FDA functions it may be applied and highlight some of the successes that the agency has had in the leveraging process?

Dr. Henney. Mr. Chairman, the issue of leveraging is not new to the agency, but it has never been used as a primary strategy where we can really extend our critical resources; not just our financial budgetary resources but our ability to

really tap into the intellectual capital--the time and energy of many important individuals and institutions around this country. This will allow us to do our job better; which is protecting and promoting the public health.

A few examples of where this has been very successful in the past, was the establishment of such a cooperative initiative with the Illinois Institute of Technology, an academic institution just outside of Chicago, regulated industry, and FDA. This has been on-going for nearly 10 years. We clearly monitor issues related to conflicts quite closely, but together I think we are able to look at issues that relate to food, particularly food packaging and safety, in an environment where not only the institutions engaged benefit but the outcome of that effort really benefits the consumer.

We have recently entered into an arrangement, called the PQRI, in which the groups will be able to look at issues related to drug and drug manufacturers. We, I think very successfully, have collaborative efforts with our partners at the CDC and the Department of Agriculture in many of our food safety initiatives. It is really by those collaborative or leveraged activities that we are able not only to stretch our fiscal resources, but also to build up the protection that we provide to consumers.

Mr. Skeen. Thank you. Ms. Kaptur.

budget request priorities

Ms. Kaptur. Thank you, Mr. Chairman, Commissioner Henney, for your very thorough testimony. I have noted that the increase you are asking for is rather substantial. It is at least a 10 to 15 percent increase over your currently appropriated level. And I know you have indicated how some of that increase is going to be spent. Could you summarize perhaps for me the highest priority increases that would be accommodated by your request?

Dr. Henney. Thank you, Ms. Kaptur. Even though the increase is substantial, our needs are also substantial. The items that I would list as the highest priority are the ones in the premarket arena that really would help us to maintain our scientific strength. They are vital to how strong we will be now and in the future as an agency.

In the area of the post-marketing arena, those things that are of critical importance in terms of safety are those related to the medical errors initiative and the Internet initiative. Right now, we are having to devote some precious resources that we would use for other things because of what we see as a real risk from rogue operators in the Internet environment. We need to have the resources needed in that area.

I think, we desperately need to get back to a position where we are able to complete our statutory obligations with respect to inspections of the industry. The statutory requirements of most of our products and industry call for a biennial inspection. These resources would get us close to that in two areas in biologics and in veterinary medicine but they would not be totally comprehensive.

The food safety initiative, is again a high priority of this committee, this Congress, and this administration. Again,

it invests in our inspection capabilities, and it also advances our research mission.

And finally, our most critical need is in the replacement of the Los Angeles lab, a lab that's over 40 years old and is unsafe. I think the chairman has actually visited this laboratory and the pictures are before you. We cannot keep pace with the kind of work that is required that we do in the L.A. lab. This lab is one of our most important port sites and the work that they do is largely on food imports. And as we all are concerned about food safety, getting a replacement lab close to the port is of prime importance to the agency. Those would be the ones I would stress.

mental illness

Ms. Kaptur. Thank you for that clarification. On page 13 of your testimony you talk a great deal about advances in medications that have been approved by FDA in different areas over the last few years for HIV, AIDS, for the elderly, for people with diabetes. One area you did not address in your testimony are the advances in medication for those confronting mental illness. I know I have asked for some additional information from your staff and they have provided it. But I wonder if you could just discuss in my remaining time here how FDA is regarding this set of illnesses, what can be done in terms of your own staffing levels, the rate at which medications are being approved versus applied for, compared to other illnesses that you approve medications and treatments for. The fact that it is absent from your testimony is troubling to me.

Dr. Henney. Let me give you our 5-year track record in terms of products that deal with mental illness. We are meeting all of our user fee goals with respect to the time frames that are expected to be accomplished for these products. We have seen four new molecular entities reach the marketplace in that time period. Ten new formulations of former drugs that were available. We clearly act from applications received and the readiness to meet us at the time of the review. I think we have staff on board right now that is adequate to meet the needs of the application load that we have. However, I would put in one plug, that not only in this area but across the board in the agency, in order to keep our scientists current with the most cutting edge science, it really requires that we start thinking about them as 110 percent FTE. They simply cannot be thought of as a sweat shop worker that continue to grind out reviews. They must have the ability to go to professional meetings, to take additional training, to interact with the academic community, to keep at the top of their game so that as they review these kinds of applications they will make right and timely decisions. So if there is any need that we have, it is in that area.

Ms. Kaptur. Mr. Chairman, I know the time has expired. I would only ask the Commissioner for the record. She made the statement that the staff is adequate to approve or review the drugs that are coming in the area of mental illness. I would be very interested in terms of the representation of that set of illnesses in our population, at what rate applications are coming to you compared to the presence of individuals affected with AIDS and the rate at which those applications are coming

to you, diabetes and the rate at which those applications are coming to you and so forth. I would be very interested why we aren't getting answers to this set of illnesses in our country.

[The information follows:]

FDA's Center for Drug Evaluation and Research--CDER--allocates resources based on the number of applications received for products to treat illnesses, rather than on the prevalence of illnesses in the population. This allows us to respond to breakthroughs in scientific knowledge about treatments that may generate many new products for particular diseases in a relatively short period of time. Our Division of Neuropharmacological Drug Products currently is the largest of any review division under CDER. Applications focused on drug treatments for psychiatric disorders are reviewed in this Division by the Psychiatric Drug Products Group, staffed by psychiatrists whose special knowledge and training is critical because of an increasing interest in exploring mental health needs in pediatric patients. In addition, a separate team of neurologists have been assigned to assess conditions of cognitive impairment including Alzheimer's disease. The Division of Neuropharmacological Drug Products has met all of their user fee goals by approving new drug applications and supplements within the prescribed time frames. Drugs for the treatment of all of the major psychiatric illnesses are the subject of very active drug development programs by the pharmaceutical industry.

Mr. Skeen. We will give you another 5 minutes after Mr. Bonilla.

food additives

Mr. Bonilla. Thank you, Mr. Chairman. I want to start out with concentrating on the requests for \$8.4 million in users fees for the direct food additive reviews. Last year, we earmarked for the first time a \$5.4 million increase for the premarket reviews of direct food additives. My questions are in this area. Why should we provide additional funds without first determining how the FY 2000 funds have been used? Another part of that is, is the FDA having any difficulty hiring additional reviewers with that money, and what assurances do we have that the FY 2000 funding we provided will result in a noticeable reduction in review times and in the backlog of pending food additive petitions?

Dr. Henney. Well, we are very appreciative of the funding that you did provide last year and we are moving quite rapidly to try to hire the kind of scientific staff that we need to do those reviews. Hiring does take time to advertise and recruit, so in the meantime we are also issuing some contracts so that on an even more timely basis we will have the access to the human resources we need to do those reviews.

We believe that we have made positive movement in this direction. We believe that we will be able to feature this as one of our major accomplishments of the next year. And we believe that a further investment in this program would allow us to essentially buy out the program. But the proof will be in

the pudding. We think that we have really come out of the blocks early and will be able to do what we said we would. As a result, we believe that this is an area where we could take on more resources.

Mr. Bonilla. But if you have had trouble getting it started already and are still looking to hire people, how can you project that you are going to need all this additional money if you really haven't gotten your feet squarely planted yet with the first round of money that you got?

Dr. Henney. I did not mean to imply, Mr. Bonilla, that we are having trouble. I was just pointing out the realities that once you appropriate the funds it does take time for us to hire and get people on board. So we have made a provision to make up for that. We are out of the block on this one.

Mr. Bonilla. So you started interviewing people then at the beginning of the fiscal year when you got the money approved and that was, what, a few months ago?

Dr. Henney. We couldn't interview people until we actually had notices out that we were recruiting. So that is the first thing that we have to do.

Mr. Bonilla. Okay. Do you see where I am coming from though? We want to know exactly what you have done with the 2000 money before anybody ever considers looking at adding a whole ton of money in the 2001 budget.

Dr. Henney. I appreciate your point.

egg safety

Mr. Bonilla. I want to move now to proposed warning labels for eggs which many producers feel are somewhat alarmist. The FDA has not published a final rule implementing this label, and the label was proposed well before the President's egg safety action plan was issued. In light of the action plan don't you think you should take another look at the warning label? After all, if producers are going to be required to implement quality assurance programs and take other proactive steps your agency may find it appropriate to propose a label that is more educational and would be less alarmist, at least according to the views of some.

Dr. Henney. Mr. Bonilla, I believe we did come out with the proposed rule in July of last year. Some of the rule dealt with the storage temperature of eggs issue, to make FDA's rule compatible with a rule that was in play by the Department of Agriculture. We did ask for additional labeling for eggs to make sure that consumers knew the risks that were inherent with eggs and to inform them that they needed to be quite adherent to food preparation rules. I believe that rule was issued, as a proposed rule. We are clearly receiving comment and will take all of those comments.

Mr. Bonilla. How does that tie into the President's egg safety action plan. Wouldn't you want to make sure that you are on the same page?

Dr. Henney. We have had public meetings around the issue of the egg safety plan in August, and we intend to have two more. I am sure that at those sessions that will be held in Columbus, Ohio on March 30th, and in Sacramento, California on April 6th we will hear comments on that point and of course we will take

those comments into consideration.

Mr. Bonilla. Commissioner, thank you. I have a couple of questions I will submit for the record. Thank you.

Mr. Skeen. Mr. Boyd.

Ephedra

Mr. Boyd. Thank you, Mr. Chairman. And Commissioner Henney, welcome. First of all, I want to start off by saying that I had a meeting earlier this month with Mr. Levitt and Ms. Plaisier and I want to commend you and them for the way they handled themselves in that meeting. They were very helpful to helping me understand the issue that I want to talk about.

We met to discuss the proposed rule on Ephedra. And basically I asked them two questions, number one, why had the law not been met in the FOIA, Freedom of Information Act, in releasing the information that you had on AERs. And secondly, I asked them why would they not consider, you would not consider withdrawing the proposed rule since they seemed to think that the proposed rule was not going to come to conclusion in its current form. The answers were, number one, is the FOIA, you did not have the resources to redact, to prepare the information for release to the public, and, secondly, that you would take under consideration the issue of withdrawing the rule.

I got a letter as to some other Members of Congress on the 25th of September in which you outlined basically three points. Number one is that the AERs would be released by March 31st, that it also would be released with an analysis, your analysis of those AERs and, thirdly, that a portion of the rule would be withdrawn. My questions revolve around this issue in this letter. Number one, what are the implications of withdrawing a portion of the rule in terms of dialogue with the public and with the industry? That would be my first question.

Dr. Henney. Thank you, Mr. Boyd. Let me respond to the many questions that you have raised within the context of this one. Clearly the issue of the rule on Ephedra has received much public comment. We received literally thousands of comments to that proposed rule. We also had a GAO analysis of the work that was done with the context of that rule that was supportive of the agency's position regarding the safety and concerns of these products but was highly critical of the kind of analysis that had gone into the review of adverse reactions.

I think what we intend to do with the time line that has been set out, is to display our review of what we have seen with respect to adverse reactions related to Ephedra that will come out coupled with our analysis. We will open that up to public comment of the widest kind, anywhere from the comments from a lay person to health professionals to scientists. We will let the science see where that takes us. I think that clearly there are particular parts of the rule that will come under analysis for change but we intend to do that as a package. But will there be a public process? Absolutely, yes.

Mr. Boyd. My question is what are the implications of withdrawing a portion of the rule in terms of your dialogue with the industry? Obviously there is a lot of information that you could glean or gather from the industry which you are not

getting now because you are basically, is the way I understand it, forbidden from having a dialog with the industry while you got a proposed rule out there. Will that continue to be the case since you have only withdrawn a portion of the rule?

Dr. Henney. The rule is proposed, it is not final. I expect and assume that industry will be part of the public conversation that we will have around the adverse event reports, and we will take those all into consideration before we move to a final rule.

Mr. Boyd. Okay. So what I hear you saying that will become--they will be involved in the public hearing process at which time you release the AERs and you have released also your analysis of the AERs.

Dr. Henney. Yes.

FOIA

Mr. Boyd. Mr. Chairman, I have one additional question I really want to pursue, the FOIA issue. Mr. Levitt, again I want to be very commending of him and the way he handled himself in the information he provided me, but basically told me that the Department was unable to provide the information public, to the public, because of its inability or lack of resources to redact and prepare for public. I noticed that in your letter on the 25th you say that you are going to release an analysis of the information. Now that must be a very detailed process that takes a lot of resources. So I assume that you had the resources to do the analysis but not had the resources to prepare it for public consumption over the last 2 years. Is that--I don't want to be unfair here but that seems, struck me as a little bit strange.

Dr. Henney. Mr. Boyd, I think it is fair to point out when Congress passed and the President signed the Dietary Supplement Health Education Act it clearly authorized us to do the work. However, there were no appropriations that followed that authorization. So as we work on issues in terms of implementing that important law, we have to draw on resources that were either already within the agency or were doing other work. So we have to spend our time quite judiciously and wisely as we do this. We have used our resources to look at an analysis, to make sure that it would be scientifically sound and that we could stand behind it, and I think that was a judicious use of the limited resources that we have in this area.

In this area of our budget that you have before you, we have asked for additional resources to undergird the kind of adverse reporting system for dietary supplements that may make this an easier process in the future.

Mr. Boyd. Thank you. And, Mr. Chairman, I will withhold my other questions until the next round.

Mr. Skeen. All right. Mrs. Emerson.

prescription drug marketing act

Mrs. Emerson. Thank you, Mr. Chairman. Dr. Henney, as you know, when we have talked about this before I expressed concern about the regulations issued by FDA implementing a statute enacted back in 1988 called the Prescription Drug Marketing Act. And as I understand FDA's interpretation of this statute,

drug wholesalers who don't buy directly from manufacturers are required to provide their customers with a detailed and complete sales history of all prior sales of drugs back to the original manufacturers and the wholesalers who buy directly from them are not required to provide this detailed sales information to the secondary wholesalers, is that correct?

Dr. Henney. Mrs. Emerson, I believe that the origins of the bill that you refer to really tried to make sure that consumers would receive a product where there was an appropriate pedigree for that product all the way through the system. This would mean anywhere from the obtaining of the bulk material all the way through receiving the finished product. And it was with that intent that these regulations were drafted.

Mrs. Emerson. So your answer is yes.

Dr. Henney. Yes, it is really the pedigree tracking of a drug.

Mrs. Emerson. And so consequently part of the sales history that is required by the FDA's final rule going all the way back to the original manufacturer includes the actual date of the sale of every shipment of the drugs and the number of containers in each shipment, the dosage, and the allotment, is that correct.

Dr. Henney. Yes.

Mrs. Emerson. Let me follow that up with more detail about that. Therefore then large national wholesalers may buy a shipment of a given drug twice a week and each shipment may contain four to six lot numbers or more. Then several of the lot numbers in the first purchase will more than likely be the same as some of the lot numbers in the second purchase, and each shipment of the drug will be placed in the same spot in the warehouse where shipments purchased in previous weeks are stored and each of these previous shipments will probably contain lot numbers that are the same as the most recent purchases separating each shipment of drugs by lot number. And date of sale in a vast warehouse and keeping track of those for resale purposes would be rather complex, don't you agree, even for large wholesalers?

Dr. Henney. It is a very complex system, but I think that Congress wanted us to go back and be able to track the pedigree again of a product, and that is the way in which these regulations were drafted.

Mrs. Emerson. Well, then, if wholesalers who don't buy directly from the manufacturer can't obtain detailed prior sales history, required information that your rule requires, then they are not going to be able to resell any product, is that correct?

Dr. Henney. That may be the case. I might ask Dr. Woodcock, who is lead of the Center for Drugs, to comment on this fairly intricate matter of the tracking of drugs and why that is so important.

Dr. Woodcock. Thank you. Yes, the issue is when the statute was written, people were concerned about counterfeit drugs, substitution of actually fraudulent products for the real drugs that were being sold. For that reason it was required when we implemented these regulations that we have the pedigree of a product, including the lot numbers and other identifiers through the chain. What you are pointing out I believe are

perhaps some consequences of requiring this pedigree that really were not commented on when we published the proposed rule. So we will certainly take this into account now as we look at the consequences of this rule.

prescription drug marketing rule

Mrs. Emerson. Particularly because of the fact that thousands of small businesses who are presently licensed to sell pharmaceuticals to rural areas like nursing--like my district to nursing homes and the like will be forced out of business. And I want to tell you all that by the end of the week you are going to receive a letter signed by me and several other members of the subcommittee and other colleagues to ask you to reopen the rule and suspend its effective date until the FDA and Congress can work together and determine how to best ensure that we are going to have safe drugs on the one hand but we are not going to put thousands of businesses out of business, particularly when so many of our constituents and others depend on the distribution of drugs in a very efficient manner. And it seems to me also that by allowing only the manufacturers to distribute the drugs we are perhaps encouraging a monopoly situation, which I don't think is your intent and certainly I don't believe--well, I know it is not the intent of Congress. But it is very, very critical that we get this done.

So can I ask if you would agree at this time to reopen the rule as it applies to wholesalers and at least suspend its effective date until we can get together to make corrections necessary so that we cannot effectively disrupt a very good wholesale distribution system for drugs and perhaps having the unintended consequence of course of driving up prices for drugs which are outrageous as it is.

Dr. Woodcock. We certainly will work with you on this issue. There is no intent to put small businesses out of business. The intent was to make sure that people are receiving wholesome and proper drugs and so we will certainly work with you on this.

Mrs. Emerson. So the answer is yes and that you would be willing to suspend the final rule until such time that we can work together to come up with a solution to this.

Dr. Henney. Why don't I respond to that, Janet. I think that we have time here, because as I understand it, the full implementation of this rule isn't until next December. I think we have a lot of time to have conversations with both you and the affected parties to see if we need to make a change here.

Mrs. Emerson. Let me just, I know, Mr. Chairman, I am sorry I am going over my time but just to make one more statement here before we conclude. Unfortunately, I think in anticipation of this rule being promulgated or finalized by the end of the year, unfortunately, some of our small distributors are already being impacted and I have here and I would like to submit for the record lots of letters from some of these small groups who have been told by the primary distributors that they don't want to do business with them anymore, that it is too complex and in anticipation of this rule that they are afraid they are not going to be able to give them any business.

So it is being felt today in spite of the fact that the rule has not been finalized.

Dr. Henney. Thank you, fair enough.

[The information follows:]

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Mr. Skeen. Mr. Farr.

generic drugs

Mr. Farr. Thank you, Mr. Chairman, and thank you, Dr. Henney. I would like to also echo the compliments of having Joe Levitt come by and visit, of the very candid and straightforward comments. I appreciate that. I think it gets us prepared for hearings like this. You have a tough job. And I was thinking last night as I was flying here probably the two Federal agencies that we put our lives in the hands of are FAA and FDA. And because you have to do such a good job, and the world is getting so tough at doing that with the Internet, and I commend you on wanting to crack down on drug sales on the Internet. The discussions we have had in our community particularly from pharmacists and doctors, this is a really big concern that people are buying prescription drugs off the Internet and being able to get permission to do that from these doctors that are essentially renegade operations. I hope you will crack down on it.

The big question here in Congress this year is bringing down the cost of drugs for people in the United States, particularly for our elderly population. And last year we appropriated some money for your Office of Generic Drugs for the purpose of trying to bring more patents. It is estimated about \$22 billion worth of brand name drugs will expire in the next few years, and the only blockade of getting those drugs into generic compounds and the opportunity to get them distributed is the opportunity to review them. That is why this committee put a \$1.9 million increase in the Office of Generic Drugs.

My question is are you on track to hire enough people to do that? How much was spent on hiring of staff this past year?

Dr. Henney. Well, Mr. Farr, thank you. At times it does seem like a tough job but it is worth doing. It takes a lot of hard work on the part of all of those people who are surrounding me today as well as a lot other people back in the agency, and it also requires your support too, for which I am appreciative.

I think to the issue of generic drugs and how we are doing, we did note that you wanted another million dollars put in this program this past year. Most of that was eaten up in our inflationary costs that we have within the agency. So we are pretty much at an even keel in terms of the number of people that are doing the work. But are they doing good work? Are they keeping up with the pace of their workload? Yes. But they are stressed. Let me give you just a couple of examples.

Mr. Farr. The question, the bottom line here with time being limited, are we going to get there? Are we going to have this huge backlog of brands names coming off their patent and

then not being able to be generic?

Dr. Henney. We have requested in this year's budget some \$2.3 million that would directly go to the Human Drugs Program that would improve scientific knowledge across the board. It is not targeted to the Office of Generics because I think we have challenges in more than just that area.

We do see a workload coming. We have been able to meet it. Last year we approved 198 generics, 40 of them were first time generics. So we are keeping pace at this point. We do think that we have a strong request, however, for you to keep supporting the kind of science we need both in the generic arena as well as in the new product lines. In terms of how fast these cycles are coming through, in 1997 it took approximately 2.9 cycles in terms of an approval process. We are down to 2.4. So we are keeping pace. It is of concern, but we have many concerns across the agency in terms of what is coming through the technology pipeline, and then what will come through the generic pipeline.

Mr. Farr. I appreciate that response. Time is running out. I think I also want to get into your highest priority risk. You have also indicated there are four priorities: Strengthening science, high priority risk, effective collaboratives and more predictable, timely, transparent regulatory process. Those are great priorities. I commend you for them. I would like to ask some questions in the next go round on the others. My time is up, Mr. Chairman, before the bell.

Mr. Skeen. That is exemplary behavior. Mr. Latham.

irradiation

Mr. Latham. Thank you, Mr. Chairman, and welcome you back, in the last year you were getting your feet on the ground, and compliment you for the job that you are doing.

Just recently on February 22, after years of regulatory decision-making, consumers were finally able to obtain irradiated red meat. It has taken a long time to get to this point but it appears there is still regulatory problems and it has to do with packaging. The FDA rule basically says that irradiation is irradiation regardless of the technology. And the FDA approved packaging for gamma but not energy beam source irradiation. It seems inconsistent with your agency's own definition of irradiation. I've got a plant in my district that is the first state-of-the-art red meat energy beam irradiation facility in the country, and the lack of approved packaging has left the industry in the horrible position that it is unable to properly package their products. And irradiation is probably the single biggest advantage in food safety in decades. And it appears again the FDA is a bottleneck as far as allowing them to function.

Can you give me an idea how soon you will be able to review and approve packaging for the red meat?

Dr. Henney. Mr. Latham, I thank you for your interest in this issue. We have this proposal under active consideration. Actually I think there was some misunderstanding or miscommunication from industry about what they would need in terms of review, but we are giving it our prompt consideration. I do want to ask our best ambassador from the FDA, Joe Levitt,

who is also the head of the Center for Food Safety and Applied Nutrition, to explain to you exactly what went on there.

food irradiation packaging

Mr. Levitt. Thank you. On the subject of the food irradiation packaging, we actually have had a very close working relationship with the Department of Agriculture and we have recently exchanged correspondence, which I would be happy to submit for the record, which would allow the packaging that you mentioned to be allowed, if you will, on a trial basis while we review the petition. The petition does fall under our expedited review. But even while it is under review, we have provision for limited use where the safety issues are generally known. In this case, we have worked out a system with the Department of Agriculture.

I have a letter that we just signed yesterday by Alan Rulis, who is the Director of our Office of Premarket Approval, and I believe that will fully address the issue--at least in the short term--that you raise.

[The information follows:]

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Mr. Latham. Okay. That is good news. So you are saying they can go ahead and function and operate.

Mr. Levitt. That is right. We also, in conjunction with the issue of food irradiation, have published a brochure, which we will submit for the record, to try and educate the public on food irradiation. As irradiation is an important tool in the safety of food, we really want to be sure that the public is fully understanding of the fact that it has been properly tested and so forth; and we have done that, again, in collaboration with a number of other organizations.

[The information follows:]

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food irradiation labeling

Mr. Latham. I guess on that very subject, and I am concerned about labeling and how it may cause some problems in the marketplace as far as people assuming it is some kind of a warning that the product may be tainted or is not safe, and I think back in the conference report of the FDA Modernization Act of '97. It required the FDA to make changes in the labeling by the end of '98. As long as the labels are truthful and not misleading, why don't you prescribe other labeling disclosures, say, you know, cold pasteurization or electronically pasteurized or something like that. You were apparently, back from '97, you were supposed to have a different label available.

Mr. Levitt. On the subject of food irradiation labeling, we did put out last year--in conjunction with the direction we got from the Congress--an advance notice of proposed rule making to take the pulse of public interest and knowledge and desires on the subject. I am afraid to report that what we got back really

showed a wide disparity of views on exactly how to address that. And so what we have tried to do is an interim measure, while we work through that, is number one, put our best talents on food irradiation on the scientific review petitions, expedited review process that we put in place last year. That process has indeed served as providing an incentive for new technologies to come to the FDA for food safety.

Second, we put out this brochure, which I would mention was in conjunction with the American Meat Institute, the Food Marketing Institute, the Grocery Manufacturers of America, as well as several others, including the American Dietetic Association, as a way of trying to educate consumers that this is a technology that they can take comfort in. And we are trying to address that in education while we work through the regulation on exact labeling.

Mr. Latham. I would like to see the brochure. I also would like to know, you know, are any consumers actually going to see it? I mean it is nice to have a nice brochure but if no one knows what is in it.

Mr. Levitt. I would hope that by having the Food Marketing Institute, which you know covers all the major food marketing outlets in the country as a co-sponsor to this, that they will be strong partners in our broad leveraging effort to get information out to consumers.

Mr. Latham. Thank you, Mr. Chairman.

Mr. Skeen. Ms. DeLauro.

food allergens

Ms. DeLauro. Thank you, Mr. Chairman. Commissioner Henney, welcome and thank you for the good job that you do. In 1996 the FDA's Center for Food Safety and Applied Nutrition notified manufacturers of its concerns regarding the labeling of foods that contain allergenic substances, in particular peanuts. We have a district meeting at Stop and Shop or Walgreens. It is not a town meeting but it is office hours. I have several families come to see me concerned about this issue of allergenic substances, including peanuts, and are scared for their kids. Some manufacturers at that time had incorrectly interpreted what constitutes an insignificant level of such foods, resulting in dangerous allergic reactions to their products. Since that date what has the FDA done to ensure that manufacturers have sufficiently addressed the problem and what are we going to try to do so it doesn't happen again. Are we moving along in trying to get products labeled so that parents know what is in them if their child happens to be deathly allergic to a particular item?

Dr. Henney. Ms. DeLauro, the issue of food allergens, are those things that represent high risk for individuals, things like peanuts, eggs, and the like. And I would again ask Mr. Levitt to describe the individual steps that we have taken and initiatives in that regard. We share your concern and the concerns of those consumers affected by these allergies.

Mr. Levitt. Thank you. As Dr. Henney said, food allergens is an issue in which we have a lot of interest. Actually if you look at our class one recalls, the number one reason would be for undeclared allergens. So it is something for which we have a constant monitoring. In addition, in our priorities document for this coming year for 2000, we have added as a new area to

focus specifically on food allergens. In particular, we said we would work to raise consumer and industry awareness to the presence of allergens in foods, and conduct meetings on labeling approaches to identify the presence of allergens. So we are trying to raise the visibility of this issue.

On the one hand, there are clear rules that certain things have to be labeled because they are known allergens. However, we realize we have to work more with the industry--on how did these mistakes happen, i.e. how does a food product that is not supposed to have peanuts get peanuts into it? We are always playing catch up. So we are looking at approaches we can take to be sure that we hit it from the front end of it, the manufacturing end, as well as from the consumer end, and to make sure there is a greater awareness and understanding of how to look for the information on the label. We try to approach it both ways. So we thank you for raising this. We think it is an important public health issue.

tobacco

Ms. DeLauro. Let me just talk about an issue that has two or three parts. Smoking. Children are able to buy tobacco products 25 percent of the times they try. The varying rate is Georgia 53 percent, Maine 9 percent. FDA has conducted over a hundred thousand compliance checks to track the issue. What can we do. I think last time you asked for money which this committee did not get to you to be able to deal with this issue of compliance and preventing youngsters from smoking. In another committee that I serve on, Labor-HHS, Dr. Klaus said that one-third of cancer mortality had dropped specifically because of prevention of smoking. Now if we have that kind of cause, and we have that kind of an effect, what are we doing at this end of it to make sure that these kids don't start to smoke so we don't have to spend the money that we are spending on research for the future and spending money on the research that we are now at the same time providing the substance to youngsters to start to smoke? So what more could you do in that area, how can we be helpful in that effort? Second, bidis, what are you doing about bidis, the cigarette from India which has at least 7 or 8 times more nicotine in it than regular cigarettes? Also, Phillip Morris, I understand from today's papers, is indicating that they would be willing to listen to some sort of regulations. Can you tell us a little bit about that or when can you tell us something about that and what direction is that going in?

Thank you.

Dr. Henney. Thank you for your questions regarding tobacco. Clearly a very important issue as it relates to our overall public health, but, particularly as it relates to the youth of this country. The data which you cite actually comes from a web site that we make available, the results of our own compliance checks. When somebody has a high rate it may mean that they are doing a good thing in terms of the checking that they are doing in their state.

We have applied the dollars that you have appropriated to us in two ways: One, to enforce that part of the rule that we can and that has to do with access. So we are doing compliance

checks. This is a partnership that we have largely with the states which gives us coverage of most of the U.S. and in many territories. Those checks are going on on a regular basis and the over 100,000 checks that you cite actually were done under the aegis of this program. Two, this year some of that money was used for an award winning media campaign to again make the point clear that tobacco, particularly when used by youth, can be addictive and very dangerous to one's health.

With respect to bidis, that has not been the focus of this effort to date. We were quite concerned particularly about what we hear from youth in their thinking that these are safe or safer, because they are, quote, not cigarettes. CDC has recently completed a survey in that regard. It may clearly lead us in a direction that we might encompass them within our compliance program. I think we also have to be aware that where these kinds of products are sold often times helps us focus our efforts.

With respect to the recent announcement that you saw, and I did in the paper this morning, I think that we will have to wait to see what is proposed and see where we go from there.

Ms. DeLauro. Thank you, Mr. Chairman.

Mr. Skeen. Mr. Dickey.

Mr. Dickey. Commissioner, thank you for coming to Pine Bluff. I do see that we have a picture of Cincinnati and Los Angeles and not of our lab in Arkansas. Is it outside somewhere, the picture?

Dr. Henney. It is being blown up as we speak, the picture I mean.

arkansas regional laboratory

Mr. Dickey. The Arkansas Regional Laboratory that you were nice enough to come and dedicate will provide the FDA with a good deal of vital research. It is my understanding that this is not complete and I would like to know if you can tell me what additional programs we will hope to get once we bring other labs into this facility.

Dr. Henney. Mr. Dickey, it was a real joy to be able to have you dedicate that facility, which is I think one not just the bricks and mortar, but what it represents, and that is really the blending of both our research and regulatory mission. I think the Congress has been very wise over the last number of years to see our facilities needs as important. And that is why we raise the critical need in our L.A. district, which is quite desperate.

We have requested in this year's budget \$3 million for some of the next phase of the Arkansas regional lab. We do, according to the consolidation plan, intend to move some of the work that has been going on in the Denver district and Kansas City to this facility. And I think that it will really take on great meaning as we are able to do that. As you are aware some of the kinds of projects we already have going on there relate to dioxin and the like are very important to our mission. So we are very happy to have that presence there.

Mr. Dickey. I am impressed, Commissioner Henney, with the cooperation that we have at that laboratory with the University of Arkansas medical sciences facility in Little Rock. And Dr.

Harry Ward is very complimentary of the cooperation that is going on and I think it is a wonderful thing. Will there be any increase in that relationship as we consolidate?

Dr. Henney. Mr. Dickey, I am always ready to take Dr. Ward's compliments. Every once in a while he throws me a criticism too and I accept both. We have enjoyed a fine relationship not only with the University of Arkansas Medical Center but other academic institutions in the area that have engaged with us in training opportunities. We do see that relationship growing, particularly as it relates to some of the work that we do in the area of toxicology at the center. And so we intend to not only continue that relationship, but let it nourish.

bioterrorism

Mr. Dickey. Thank you. Next subject chemical or biological weapons of mass destruction. You have asked for \$11.5 million to address this segment of your concern. How does the FDA intend to use these funds and what unique ability does the FDA feel that it has that it can add to this serious problem?

Dr. Henney. Well, the bioterrorism effort in this country is really multi-agency. For the FDA, the work is really concentrated in three areas: One, within our Center for Biologics. As new vaccines might be developed we need to be prepared to readily and appropriately review those kinds of applications and also engage in doing work in terms of some vaccine development with our colleagues from other Federal agencies. That is a long term process. That is not overnight. But we need to begin to invest in that arena.

Our Center for Drugs would also be engaged in looking at some of the stockpiling issues. And at NCTR much of the work, as you know, is also looking from a research perspective at some of the products as they would be related to either neurotoxins or products that could be used and end up in the food supply. So those three parts of the agency would be most heavily engaged in the bioterrorism effort.

Last year, as you know, our appropriation was linked and carried with the Department's request to Labor-HHS. Unfortunately, they saw an FDA request as not theirs. We have made some accommodations to still stay in the game this year, but to have an ongoing effort in this we really need your support.

Mr. Dickey. Thank you, ma'am.

Mr. Skeen. Mr. Nethercutt.

bioport facility

Mr. Nethercutt. Thank you, Mr. Chairman. Commissioner, welcome, gentlemen, glad you are here. A couple of areas of inquiry, one involving anthrax, the other involving the issue of insulin for diabetics. In November last year the Food and Drug Administration Office of Compliance and Biologics filed a Form 483 following an inspection of the Bioport Corporation, which manufactures the anthrax vaccine, and a number of serious problems were observed during the inspection: Documentation and reporting was inadequate, the manufacturing process was not

validated, lots and sublots of the vaccine failed specifications and were contaminated and lots failed potency testing. And numerous aseptic failings were observed and temperature limits were not established. It is a nine-page report. The Commissioner raises serious questions about the ability of Bioport to manufacture safely this vaccine, which is an important vaccine. I am wondering if you could advise the subcommittee of the status of the FDA approval for the facility, the Bioport facility.

Dr. Henney. Mr. Nethercutt, we share your concerns. We don't take lightly the need to assure safety by making sure that the conditions under which any products are made follow good manufacturing practices. It is through that mechanism that we can ultimately assure safety of a finished product. I believe that the Center for Biologics has been engaged with the BioPort about what needs to be done in terms of an actual progress report. I would appreciate providing you an update for the record.

[The information follows:]

The BioPort facility in Lansing, Michigan is continuing to implement a strategic plan for compliance submitted to Center for Biologics Evaluation and Research--CBER. The most recent inspection of the Anthrax Vaccine Adsorbed--AVA--manufacturing facility was conducted in November, 1999. This inspection resulted in an extensive list of inspectional observations. Following FDA's inspection and review of the BioPort supplement for the renovated inspectional facility, FDA sent BioPort a complete response letter in December, 1999.

We have met with BioPort and the Department of Defense several times since that letter was issued, and BioPort has presented various portions of their response, including a time line for validation of the manufacture of AVA. When the firm has completed all submissions to respond to the inspectional observations and complete response letter, we will review these submissions, conduct an additional pre-approval inspection, if needed, and respond to the submission with either an approval or an additional complete response letter. Until the supplement for this facility is approved, newly manufactured vaccine cannot be distributed for the lot for sale.

diabetes and insulin

Mr. Nethercutt. I appreciate that. With respect to the issue of diabetes and insulin supplies, you may know I have been involved with other Members of the House in trying to meet the needs of diabetics in this country and cure this disease and it is a condition that needs a cure. About a year ago we discussed this issue of beef-pork insulin. I appreciate your easing the importation process so that people with diabetes who feel their body has stabilized better with beef-pork insulin can import it from abroad. That is positive. The U.S. Department of Agriculture has also simplified the forms that USDA requires for personal importation. But there is a problem, it does remain costly and burdensome and for some users. It is a life line for many people who have been accustomed to beef-pork insulin and feel as though it is their only way to feel

good and live well. There is a problem of supply in this country.

I am wondering if you have taken or are considering any steps to ease that process, make it simpler for people who are dependent on beef-pork insulin.

Dr. Henney. Mr. Nethercutt, yes, we are well aware of this issue of diabetics who feel their disease is better controlled on beef insulin rather than relying on the alternative of pork insulin or the human derivatives types of products. We have had a staff member working quite closely with this group to keep them informed about what we have going in this area. Really the situation, as you know, arose when a company in this country decided to stop manufacturing this product because they saw a shrinking market share as many diabetics convert to other products and also because of the concern about BSE in the source supply of beef insulin. There are really no domestic manufacturers at this time. We are trying to work with any foreign manufacturers that might be willing to provide a source. We have allowed enforcement discretion up to a 6-month supply for the personal importation of this product. But we have to work on what comes to us and we are trying to do that.

Mr. Nethercutt. If I might just close by stating that I have an extraordinary number of people communicating with me on this issue. There are people here today who are very concerned. I would request that perhaps you would be able to take a few minutes at some point to meet with these folks at least to get a better sense of the problem, or give some thought to the idea that an emergency could be declared perhaps by the Secretary of Health and Human Services to allow this importation. It is of serious personal consequence to a lot of people. I think they want to be sure that the diabetic community wants to be sure that you have a sensitivity to this issue and that the agencies of government who have jurisdiction over this also do and should have, in my judgment. I would appreciate that you would be willing to consider the dependable supply issue.

Dr. Henney. Thank you.

An unidentified member of the audience. Mr. Chairman, can I address or say something just for a moment please about the BSE issue? There is no BSE in insulin that comes from the U.K. Because those pancreases, that beef comes from the United States.

Mr. Skeen. Would the lady please take a seat. We will get to you later.

An unidentified member of the audience. I am sorry.

Mr. Skeen. That is quite all right. Ms. Kaptur.

foreign drug purchases

Ms. Kaptur. Thank you, Mr. Chairman. Commissioner Henney, last evening I was with several doctors in my home community who told me that they refer many of their patients to Canada to purchase medications, which cost far less than most medications do here in the United States. I don't know from my colleagues that serve at the U.S.-Mexico border whether their doctors do the same thing. When you and I met several weeks ago, I asked the question about the safety of drugs purchased in other countries by U.S. citizens and you indicated some skepticism as to the safety of those drugs. Here I have doctors from my

community referring people to Canada and I repeated what you had said to me about ingredients and the possible differences in the constitution of those drugs, and the physicians basically said to me but, Congresswoman, they have an FDA up there in Canada too.

So my question really goes to the heart of how many complaints has FDA received in a given year relative to medications that have been taken by U.S. citizens where they have had very bad effects from those and to what extent do you measure where those drugs were purchased, whether they were purchased in Canada or Mexico or Cuba or wherever they might be. I was very surprised at the referrals being provided by physicians back home quite frankly.

Dr. Henney. Ms. Kaptur, I would love to be able to provide you with that information but that is not necessarily the kind of information we collect. We do collect adverse reactions but being able to know precisely where a product was purchased or whether it was purchased in this country or elsewhere is not necessarily within our data scope right now. Canada certainly does have a very active FDA and we interact regularly with that regulatory body. However, there are drugs that are manufactured in Canada that have a different biological activity, than drugs that are manufactured here. So you may be getting a more or less potent drug. From other countries we might have greater concerns about whether you would be getting a counterfeit or a contaminated product. The issues are real. How many adverse reactions we have actually seen from that I just do not know.

Ms. Kaptur. Who would keep such data?

Dr. Henney. Who would keep?

Ms. Kaptur. Within the government of the United States who would track if a consumer goes to Mexico or goes to Canada and purchases a drug and something goes haywire; where does one go?

Dr. Henney. I am not sure that there is a government body that does that. I could ask Dr. Woodcock if that information sometimes appears on our adverse reaction reports but I believe, it would not.

Dr. Woodcock. That is correct. Consumers and pharmacists and physicians will report adverse events to the FDA. They could have in their written material that it was purchased in some other country but actually they are probably unlikely to do that. And we do not have data that analyzes the adverse events in that manner.

Ms. Kaptur. I find this omission somewhat striking. If we are having trouble with imported food, we are very concerned about people purchasing items that may be harmful. We have bodies of this government that worry about the safety of children's toys, and yet if we have citizens purchasing drugs and they may not be warned, if nobody is collecting data that means nobody is being warned either. And if doctors are referring people all over the place, as I was very surprised to learn--I am going to submit some additional questions to the FDA as a part of the record. Perhaps there is something that could be done somewhere to provide a greater level of sophistication here and reporting if people are actually being encouraged to purchase elsewhere and what those effects are. Perhaps FDA is not the agency to do that, but I am very surprised that this isn't somehow monitored.

Dr. Henney. There are two issues coupled here I think, Ms. Kaptur. One is the issue of the kind of data that we would request or require when an adverse report would come in and whether we would be able to validate that or not. It is also linked a bit to this issue that was raised before about the ability to truly track a pedigree of a drug. And so I think there are two issues that are coupled here and we will be glad to respond to your question.

[The information follows:]

There currently is no mechanism to track these personal purchases. If an adverse event occurred due to a drug purchased in the foreign country, it can be reported and monitored by FDA through our MedWatch program. If it can be determined that the product originated in a foreign country, FDA can communicate serious events regarding a foreign drug with FDA's counterpart in the foreign country.

Ms. Kaptur. Thank you, Mr. Chairman.

Mr. Skeen. Thank you. Mr. Kingston.

pdufa

Mr. Kingston. Thank you, Mr. Chairman. Ms. Henney, it is good to have you back at the committee again. I regret we had another committee that started at 10:00 that Mr. Nethercutt and I had to go to so we were late. First of all, give you an opportunity to brag, this may have been brought out but I understand that on the prescription drug approval process that you have cut that to me down to 12.9 months. And I think that is great. In the past I think it has been longer. I have heard up to 8 years. I am not sure what it was, but I just, you know, open with a friendly comment on that. If you want to say anything that would be up to you.

Dr. Henney. Well, Mr. Kingston, I appreciate being back before the committee. I also appreciate being able to provide you with a report card on our effort to meet the requirements of the Prescription Drug User Fee Act. It is a lesson that demonstrates when the agency is properly resourced we are more than able to do our job and do it well. I think prior to the Congress' passage of that act in the early 1990's average review times were 30 months, sometimes 36 months. We have cut that down for both drugs and biologics to a little under a year. We are not only proud of the track record in terms of timeliness, but the kind of products that we are reviewing, I think are providing real benefit for the population and it is good to do that for the public health.

cochlear impant device

Mr. Kingston. I think all Members of Congress commend you for that. They are using this drug in Canada, we hear that so often, or it is safe elsewhere. So I think 12.9 months is really great. So a question that I have which I believe you are familiar with has to do with this cochlear implant device for hearing impaired and has to do with a constituent of mine who is working with FDA on it. And I was wondering if you could

give me an update. I can read some background on it but if you just want to.

Dr. Henney. Mr. Kingston, at this point in that particular application, most of the information is still seen as confidential trade secret. So we are not permitted under those rules, unless the company gives us permission, to talk in a public session about the application. If the committee would desire to go into executive session we could or we would be glad to come down and brief you individually about what the issues are there.

Mr. Kingston. That might be good. I do understand that your staff has been working with my staff on it and I believe that they are making progress and things are going well. The people involved with all that here have been very frustrated, as you know, and so--but I also know there is always two sides to a story. But it is something we are interested in because I think it would help lots of people. And I have among other things a mother who is hard of hearing. I know as many items as we get out there on the market for hearing impaired people to choose from I believe it is in the interest of all of our constituents and everything that we are trying to do. So I would like to continue this dialog with you in the appropriate forum.

Dr. Henney. We would be delighted to do that.

[The information follows:]

Your constituent appears to be interested in trials of experimental cochlear implants. The design of trials to demonstrate safety and effectiveness of new implants and provide new options to otolaryngologists and their patients is a high priority for the Agency. We would encourage your constituent to work through the manufacturer with FDA.

Mr. Kingston. Am I out of time, Mr. Chairman.

Mr. Skeen. No, not yet.

Mr. Kingston. On the food safety initiative, I don't know which one of you wanted me to run out the fastest.

Mr. Skeen. Are you taking bets?

food safety initiative

Mr. Kingston. No, I have learned, Mr. Chairman. But the President's Food Safety Initiative, FDA got 79 million increase last year asking for 30 million this year. In terms of quantitative measure, which I know is very hard, but have we seen a corresponding reduction in food borne illnesses or what kind of reductions have we seen? What have we gotten for our money? That is all I am asking.

Dr. Henney. Mr. Kingston, I think what this country and the American people have received from the food safety initiative has been a tremendous amount in terms of our capacity to deal with several issues as they relate to food safety. Perhaps those issues that create the highest risk are microbiological contaminants. I believe that we are able to track issues related to food safety better than ever before. We have put a tremendous amount of effort through the President's Food Safety Initiative into research, the PulseNet, and the FoodNet programs that have been jointly sponsored by the Agriculture

Department, the Centers for Disease Control and ourselves. I think the list is very long and I would love to supply that for the record for you.

[The information follows:]

The President's Food Safety Initiative has sought to establish preventive systems such as the Hazard Analysis Critical Control Point--HACCP--in domestic seafood processors, Good Agriculture Practices, and intervention technologies such as sprout producer guidance. It has established educational messages such as egg safety campaigns for food handlers and consumers, and food safety campaigns for senior citizens, who are a higher risk of developing foodborne illnesses. Research and risk assessment has improved to better understand and target foodborne hazards such as *Listeria monocytogenes*, especially for pregnant women, development of methods to detect *Cyclospora*, *Campylobacter*, *Vibrio parahaemolyticus* and a rapid screen that identifies twelve common foodborne pathogens. Surveillance systems, such as the National Antimicrobial Resistance Monitoring System--NARMS--which monitors for resistance to antimicrobials, are used to combat foodborne bacteria that cause disease in humans. The Food and Drug Administration has also collaborated with Mexico to help them develop the first international human and animal monitoring system for foodborne antimicrobial drug susceptibility surveillance in the Americas. Based on CDC's estimates of 5,000 deaths and 76 million illnesses per year, foodborne illness remains a major public health problem. In dealing with these significant public health issues, the Food Safety Initiative funds have contributed significantly to the federal government's ability and capacity to move on multiple fronts and afforded resources to build prevention systems, enhance current system capabilities while responding promptly to outbreaks from foods produced domestically and abroad.

The overall picture of trends for food safety knowledge and practices that emerges from research is quite encouraging. Between 1993 and 1998, the public's food safety practices, both the consumption of risky foods and food handling behaviors in home kitchens, show dramatic improvement. For example, for the population as a whole, the incidence of eating pink hamburger is down 33 percent and the incidence of eating raw oysters or clams is down 39 percent. The safety of reported hand-washing and cutting boards practices has also improved markedly. The improvement is particularly strong for handling meat or chicken, which improved 74 percent compared to a 27 percent improvement for fish. Knowledge levels about microbia food pathogens increased, along with rising perceptions of the possible risk of getting foodborne illness.

That is not to say that there are no consumer education issues to be addressed. There are obvious gaps in consumer knowledge, attitudes and practices related to food safety. For example, most consumers still do not handle eggs very carefully and they are more likely to consume undercooked eggs or foods containing raw eggs than any other risky food. Most consumers have never heard of *Listeria* or *Campylobacter*, which are at least as prevalent in the food supply as the more well known pathogens, *Salmonella* or *E. Coli*.

The Food Safety Initiative has provided necessary resources for FDA to undertake the enormous challenge of foodborne illness. However, even more is expected of this Agency.

food inspection

Mr. Kingston. Okay, Mr. Chairman, I yield back. I do want to say one of the things that we on this committee, and on both sides of the aisle, we are very concerned about food safety but we really want government agencies to work as partners in technical assistance with food processors rather than kind of an "I gotcha" approach, which we do see from time to time in certain agencies with certain food inspectors and people on the line. And I just bring that out.

Thank you, Mr. Chairman.

Mr. Skeen. Thank you. Mr. Boyd.

Mr. Boyd. Thank you, Mr. Chairman. And Commissioner, sitting here listening to all the questions, that myriad of issues, you really do have a tough job. And I commend you for the way you conduct yourself.

Dr. Henney. You want to tell the President that I need a raise?

ephedra

Mr. Boyd. I am not sure I would go that far. Commissioner, in your testimony you state, and I quote, the FDA--I want to go back to the Ephedra issue here because I didn't have time enough to finish it. "The FDA Modernization Act directed the agency to consult with stakeholders on an ongoing basis and to keep them apprised of our strategies in new product decisions and to generally make them informed participants in our regulatory process." and I assume that stakeholders means the consuming public in the industry probably would be the----

Dr. Henney. Yes.

Mr. Boyd. Now, certainly as I told you before, I applaud the decision of the agency to withdraw portions of the proposed rule on the Ephedra. I am not sure I understand exactly what that means at this point in time. But I am sure at some point in time Mr. Levitt is going to tell me. And I would ask you this. In light of that statement, that quote out of your statement, wouldn't it make sense to try to gather all of the information that you can before you present publicly an analysis of the AERs, wouldn't it make sense to listen to the public in that public forum, all the stakeholders, including the consuming public and the industry, any information that they might have that might help you make a more thorough and appropriate analysis?

Dr. Henney. Mr. Boyd, I can assure you that we will be receptive to receiving that kind of information in the public meeting. We are always open. I think our mailboxes are full of people who want to provide us with information that they have with respect to any issue that we deal with. We have to pace ourselves in terms of how we respond, that is why we have designated this particular time period in which we will share the analysis and look for reactions or additional information.

Mr. Boyd. But my question was, wouldn't it make more sense

to withhold the analysis until you have benefit of that information?

Dr. Henney. I don't know, Mr. Boyd, if there is some information that we do not have in hand at this point. I think Mr. Levitt and his staff have met numerous times with industry, and has encouraged them to bring forward any information that they might think is relevant. But if they still have some out there, we of course are glad to receive it.

food safety audits

Mr. Boyd. Okay. I will shift gears. Go to another subject. I note from time to time that your agency has visited foreign countries to audit the safety of food produced in those countries that are being exported to the United States. Now, we go to great lengths in this country to ensure that our consumers have access to a safe and healthy food supply. We have standards for poultry and beef and we often ban the use of certain pesticides in the name of food safety, not only in the name but practically to provide a safe food supply. That makes it more costly for our U.S. producers and consumers obviously, but we think it is well worth it.

Now, would you elaborate to us about your efforts to audit other countries, other ag producing food producing countries which are exporting to the U.S.? And I will ask a series of questions here: Which countries have been audited; which particular food product was the subject of that audit; are written reports prepared on the results of those audits; are they available to the public? If not, why not? Has the FDA ever been denied access to a foreign country in which we want to conduct an audit?

If you can't answer all the those in the time remaining I will submit those for the record, Mr. Chairman.

Dr. Henney. I will try to put myself on fast forward but I am not sure I have time to answer them all. Within the limits of our resources which we have to use wisely, we do look at the whole issue of an increased amount of food that we regulate coming into this country. We have tried to do this judiciously by setting up mutual recognition agreements with some countries that we know are large exporters to make sure that our regulatory capacity may be similar or equivalent. Those kinds of understandings are in their earliest phases of negotiations because they have to be sure of us and we have to be sure of them. We have made a commitment to inspect some of our highest risk areas of production. We have also tried to increase what we do in terms of inspections at the border and be smarter by looking at products that are of particular high risk or importers that have been problems in the past.

We have undertaken this past year a tremendous outreach effort of technical assistance to countries so they will know what our expectations are of and for them. This has gone on in Mexico, Latin America and some countries in South America.

So it is that kind of outreach, so that people know what your standards are so that you can educate them about those standards and then you can inspect against the standards that really keep a program strong. Do we have the kind of resources where we could be in every country at every plant? No. There is

no way. That is why we have got to target and limit and be smart about what we do.

Mr. Boyd. Thank you, Commissioner. What I would like to do, Mr. Chairman, is submit some of these specific questions to which Commissioner Henney didn't have the time to answer and submit them for the record.

Mr. Skeen. Thank you. It will be done. And let's have Mr. Latham.

irradiated foods

Mr. Latham. Thank you again, Mr. Chairman. I don't know if I really got an answer to my earlier question about labeling on irradiated foods. Is there any plan or proposal or thought at FDA about allowing different labels such as electronically pasteurized or cold pasteurized or anything; is there any plan thought of that?

Dr. Henney. Taking those specific words into account, I don't know of a specific plan. However, in educating the consumers about irradiation, I think we need a much more extensive and comprehensive plan, particularly as we deal in this public-private partnership to educate consumers about what irradiation does and what it can mean for food safety. Quite frankly, when I was down in the Miami district knowing what some of their initiatives had been in terms of trying to educate consumers about irradiation and its beneficial effects, I saw as quite positive. I hope we can emulate those kind of things.

food additives

Mr. Latham. But I guess the answer then is no, there is no effort to approve of any other label. Okay. Last year they announced an intent to go to give priority reviews to food additive petitions having to do with say hot dogs or luncheon meats, ready to eat. How quickly does FDA intend to act on the pending petitions as far as irradiation petitions and can we be assured that it won't take 5 years like it was on red meat.

Dr. Henney. Mr. Latham, Mr. Levitt has a very intense effort in terms of strategic planning and having people keep to time in terms of performance and I will let him describe some of his priority setting for those specific issues that you raise.

Mr. Levitt. What we have put in place is a series of goals, actually in all of our programs, but, in particular for food additives. In the expedited review that you mentioned, our goal for this year, is quite ambitious but I believe appropriate. For the petitions that we got in fiscal year 1999, our goal is to complete, within 360 days of filing the safety evaluation, 80 to 90 percent of food and color additive petitions that qualify for expedited review. So we are saying, within a year of filing, we will try to do nearly all of these--i.e., 80 to 90 percent. We are getting an increasing number of these petitions, but, we believe it is important, as I said before, both to create the incentive for companies to bring those technologies to the FDA, and for us to position ourselves so that we can review those rapidly. We also have put out our

report card from last year, which shows I believe that it is important that we not only say what we are going to do, but be willing to report on what we actually did or didn't do. Last year, we were able to complete nearly 90 percent of all the priorities across CFSAN.

food biotechnology

Mr. Latham. As far as GMO's and biotech, do you plan to initiate any revisions or proposed changes to your existing review process, and I think very importantly, labeling policy as far as biotech foods? If so, what are your next timetables and what are your next steps and have you made any preliminary decisions as to what changes would be made and also what additional funds you would need to do it?

Dr. Henney. Mr. Latham, with respect to the issue of foods that have been developed using the tools of biotechnology, we have had in place a policy since the early 90's that spells out how the agency deals with issues related to these products anywhere from their review--to how we interact with the industry in terms of the consultative process before they come to market, to which ones of these products we require labeling on. A piece of that policy also spells out that the industry can choose to voluntarily label if they so desire.

Recently we have had cause to really listen again to the public about where we are on that policy. I think it started really because of what was happening in Europe and a lot of the surrounding trade issues. It was clear that there was a cause of concern or at least expression of concern in this country as well. We had been lulled into doing our business in a very quiet way. We felt like we had very strong compliance from industry in terms of the consultative process. The things that were on the market we saw as being appropriately there, but that very few outside of the agency were aware of what we were doing. So we were certainly not as transparent as we would like to have been.

We also heard concerns from industry and stakeholders. As a result, we decided to revisit the policy. We held three open meetings over the course of this fall, public meetings, and they were held in Chicago, Washington, and Berkeley, California. We listened to all of the concerns expressed there. We have also had an open docket to which we have received over 25,000 comments about the issue of bioengineered foods. We looked and we sought answers to questions in two areas. One is: are there safety issues that should cause us to rethink or revisit this policy, and two: how do we provide information to consumers about bioengineered foods, anywhere from the labeling which is popularly raised, to other means of communicating this information to the public.

It is fair to say with that amount of input we are still deliberating on this matter. I think I would hasten to say that we heard very little about those products that are on the market in this country in terms of their safety. And that was reassuring.

There may be issues related to the science of future or developing products, issues related to how we provide information to consumers who want to make a choice about what

they eat for whatever reason, issues related to environmental concerns, issues related to food safety, and the issue of individuals who just want to know if the product has been changed or modified in any way. Clearly we hear this more as we go into the European nations. From developing countries we hear do not do anything to disturb this technology, we need it for our health and we need it to feed our nation's people.

So those are the gamut of issues that we are dealing with right now and we will be glad to keep you involved as we would go forward with any changes in current policy.

Mr. Levitt. If I might add one footnote, you will find in the budget a request for an additional one and a half million dollars for food biotechnology that will be shared by my Center, the Center for Veterinary Medicine and the National Center for Toxicological Research down in Arkansas.

Mr. Dickey. Say that again.

Mr. Levitt. National Center for Toxicological Research down in Arkansas.

Mr. Latham. He just wanted you to say Arkansas.

Mr. Levitt. We really feel that we need to have resources as in all areas, not only to maintain our expertise and enhance it, but be on the cutting edge of this particular area. We want to be sure that we are viewed as world leaders in the science of biotechnology.

Mr. Latham. It is an important issue and this is going to affect a lot of areas, including trade and everything else.

Mr. Skeen. Put a label on that ``to be continued.'' Mr. Farr.

genetically modified organisms

Mr. Farr. Thank you, Mr. Chairman. I want to ask a question. Before that I want to echo Mr. Latham's concern. I just had a meeting with industry folks and the university folks on GMO's and I tell you if we don't make this more transparent than we are, this is going to be regulated from the streets. And it is going to be regulated by state initiatives. And California is very famous for being able to be successful for those initiatives. And that is the biggest market in the United States or the world that is going to be regulated and it is all going to be because people have lost confidence in government.

So my point is that you have got to make this transparent. You have to get people that are in the scientific fields out in the streets talking with consumers. My question really goes to the issue of how you prioritize. You talk about we must address the highest priority risks. You also point out the FDA is a regulatory gateway through which an estimated \$50 billion in biomedical research must pass and be judged and you also state you don't have enough FDA assets alone to address the complex risk management challenges. So in this, how do you determine priorities. I have concerns with this because we have some, dietary supplemental manufacturers in our district and a lot of them in my district and they are concerned about regulations putting them out of business. On the same hand you have those that--Congresswoman DeLauro's concerns about if it is not properly labeled adverse. So how do you prioritize? And make sure. Why, for example, is Ephedra one when we don't even know

or do we know, how many Americans consume Ephedra?

Dr. Henney. Mr. Farr, I think your question goes to the heart of how do we set priorities. Also in my testimony what I tried to express is that our priorities are set on looking at what threatens the public health and that is the whole issue of risk based analysis. We also set priorities on what scientific assessments tell us to do.

Mr. Farr. Is that a marketplace determination? We are in this dilemma. Here we are in the Agriculture Committee. What is happening in agriculture is called fresh to market. They harvest it right in the field, put it in a bag in the field and tomorrow it is delivered anywhere in the world because we can do that. I represent all these speciality crops, strawberries and lettuce and all that stuff. And all things as you go down in the market here in Washington you look at it, it is all from the Salinas Valley. How does it get here from the day after its harvested in the fields? Because everything is done there. So on the other hand you are having risk capital go in, we want to be in this business. But the worst thing that could happen to businesses like that is all of a sudden say, oh, this fresh to market is unsafe. Then they are out. Government is still around. So how is it--we don't depend more on marketplace reactions?

It seems to me there is a cause and effect here. If there is thousands of people, millions of people doing something and there is very little adverse effect, that it wouldn't have much of a health risk.

Dr. Henney. Oftentimes there is very little effect because we have put in good preventive control measures to make sure that those bad things won't happen in the first place. We need to also have a capacity to intervene when we do see risk in the marketplace to move rapidly. But one of the reasons----

Mr. Farr. Let me give you an example where government has done both. On the science side we told everybody to use reclaimed water. We said the tests show you can use reclaimed water on agriculture. If you clean it up to a certain level, almost drinkable level--we don't allow that yet but that level, you appropriately apply it to these crops, that they will be fine. On the marketplace because competitors don't like that because you are growing a crop that they want to sell too, they are going to try scare tactics. Government doesn't seem to come in and defend those people that are using reclaimed water. They have led them down the path in saying this is okay to do it but now that there is an alarm in the field, that we don't defend them. And that is the kind of balance that we need to look at, is more appropriate applied enforcement. I guess my time is up, Mr. Chairman.

Mr. Skeen. I believe it is. Mr. Dickey.

Ru-486

Mr. Dickey. Commissioner Henney, you have given a conditioned approval to the drug RU-486. And there is further study being made. Is there any being made on the psychological effects of the drug on women or the long term medical consequences by your Department?

Dr. Henney. There is--let me ask. Mr. Dickey, you asked me

specifically if there were any research like that going on in my Department. The answer to that, is no. What I was consulting Dr. Woodcock about was did she know of any research like that going on anywhere. I think what we would have to do is go back to our European colleagues and see. Neither of us know if that kind of research is ongoing or not.

[The information follows:]

The primary clinical trials conducted by the sponsor to support the safety and efficacy of mifepristone--RU-486--were discussed before the Reproductive Health Advisory Committee in July 1996. These clinical studies did not include an evaluation of the psychological effects of the drug in women or an evaluation of the long-term medical consequences of the drug in women. FDA is unaware of any published studies on the psychological effects or the long-term medical consequences of mifepristone in women.

cecure application

Mr. Dickey. Could you do that. Could I ask you to do that? There is no rush on it but just some report in that respect. I would like to mention something to you that I have mentioned before and that is Cecure, there is an application before your Department about that. Can you tell me the status of that?

Dr. Henney. Mr. Dickey, I think, as I mentioned to Mr. Kingston, much of the material that we receive from a company must remain confidential in terms of trade secrets kind of status. I think that if the committee wants a briefing on that matter we would have to go into executive session or we would be glad to keep you apprised on what the issues are, Mr. Dickey, individually.

Mr. Dickey. I appreciate what you are saying. The thing I need is just the time as to when you project that we might get some response or my constituent might get some response. We can do that apart from here.

Dr. Henney. We are working actively on that and I will get back to you in terms of when we might have a response on it.

[The information follows:]

One firm has submitted a generally recognized as safe--GRAS--notice to inform FDA of its view that the product Cecure is exempt from premarket approval for use as an antimicrobial because that use is GRAS. We provided a response to this firm today, February 29, and have scheduled a meeting with the firm on March 31, to further discuss issues related to this GRAS notification.

Mr. Dickey. Thank you. That is all the questions I have.
Mr. Skeen. Ms. DeLauro.

Tobacco

Ms. DeLauro. Thank you, Mr. Chairman. Commissioner, what I will do and I don't want you to have to go through this again, is just have my question submitted to you, if you wouldn't mind to lay out with the additional funds that you are requesting

for the tobacco prevention efforts what would that allow you to do, how much stronger, or weaker we might be in this process. But I want to know what would this in your estimation allow us to do in terms of preventing youngsters from starting to smoke?

Let me ask a couple questions if I might. A constituent of mine, Mark Mushin, is the father of a child with Canavan's disease, a hereditary brain disease that affects very young children. The average life-span of Canavan's child is 5 to 10 years. Just in terms of these kinds of illnesses what is the time span for reviewing potentially life saving drugs especially for such rare diseases? How do you prioritize which therapies to review?

PDUFA

Dr. Henney. Ms. DeLauro, in this kind of situation, the FDA Modernization Act and the Prescription Drug User Fee Act speak to this issue of serious and life threatening illness. We have very tight performance standards to meet and in this area the review time is on average less than 6 months from the time we begin application review.

medical device reprocessing

Ms. DeLauro. On February 11th, the Hartford Courant reported that the FDA is considering raising the safety standards for the reuse of medical devices. One of the concerns I have is about the need to balance quality patient care with cost savings. Do you know of any data that indicates that people have actually been injured or put at increased risk by the means of single used devices?

Second, does the FDA have all the authority that it needs to effectively regulate the reprocessing of medical devices labeled for single use. And, third, have the FDA's quality system regulations that regulate third party reproprocessors been working to protect the public sufficiently to ensure that safety of these reprocessed medical devices that have originally been labeled for single use?

Dr. Henney. Ms. DeLauro, I would ask the Center Director David Feigal to come and elaborate on your three questions. I think that we do have authority in this area with respect to reproprocessors that are spoken to in our basic food, drug and cosmetic law. We are in the process of--and very active process of looking at this issue again with risk-base analysis, that is where people are at most risk--and we make sure we devise an appropriate regulatory scheme. But I will let Dr. Feigal explain that.

Dr. Feigal. The question often comes up whether or not there have been injuries and, in fact, there have been some reports, but in general they are the same types of injuries that occur when the devices are used new. Part of the problem is it is difficult to tell when a device has been reused. But even if there weren't injuries we would still be concerned that devices would perform satisfactorily, that they would be well manufactured devices, and that they would meet the quality systems requirements that you alluded to.

We do inspect the third party reproprocessors. Some of them

actually haven't recognized that we have jurisdiction over them and we are in the process of finding some of them in order to begin this process. The warning letters that have been issued for that are public. There have been 11 of them in the last year and we are working with that segment of the industry to make sure what they reprocess will result in devices that are safe.

Ms. DeLauro. Thank you very much. Thank you, Commissioner. Thank you, Mr. Chairman.

Los Angeles Lab

Mr. Skeen. I think this just about gets us to the final stages of this thing. I will close it by making some comment. We had a discussion about the laboratory in California. It is really a disappointment to me in the travels that I have made throughout the country and overseas and so forth that the laboratories that we are getting the sizes are not adequate for the work that we are getting done today and the requirements done today. I don't know why we haven't kept up with the modifications to make us, to give us the tools to work with. And the laboratories I think are very important. Well, there goes another deal, we can make a big investment in it. But I think the science that you are dealing with today has to have a better laboratory base from which to work on it. They are not getting equipped with better equipment and state-of-the-art. But I just want to tell you that people in these laboratories are top notch. Plus given the stuff to work with, I know it is expensive, but it can be done. We have--we are just not giving our folks the tools to work with. So thank you for what you do and how well you do it, and your Department and the rest of it. We appreciate that.

So without any further ado, thank you very much.

Mr. Farr. We can submit questions for the record.

Mr. Skeen. Absolutely. Thank you.

prescription drug marketing act

Clerk's Note.--FDA has delayed the effective date of some provisions of the Prescription Drug Marketing Act. The Federal Register notice regarding this matter, published May 3, 2000, is on page 1362 of this volume.

Tobacco Jurisdiction

[Clerk's Note.--The following statement explains the March 21, 2000, Supreme Court decision on FDA's authority over regulation of tobacco.]

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